AUG 1 4 2000

510(k) SUMMARY

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K00 1967.

Submitted by:

InVitroCare, Inc.
11408 Sorrento Valley Rd.
Suite 202
San Diego, CA 92121
Telephone: (858) 452-1986
Facsimile: (858) 452-1828
E-mail: Info@invitrocare.com
Contact: Robert E. Lovins, PhD
Date Submitted: June 28, 2000

Device Identification:

Trade Name: PVP-Polyvinylpyrrolidone

Common Name: Sperm Immobilization Medium

Classification Name: Reproductive Media (21CFR, 886.6180)

Predicate Devices:

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335 and 510(k) Reference Numbers K991391 and K991343

Description:

InVitroCare's Polyvinylpyrrolidone (PVP) reagent is composed of polyvinylpyrrolidone (MW:360,000) dissolved in a combined sodium bicarbonate/HEPES ([4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid]) buffering system and is appropriate for those procedures that do not use a carbon dioxide atmosphere.

Intended Use:

Polyvinylpyrrolidone reagent is intended for use as an aid in the immobilization and isolation of individual sperm cells prior to intracytoplasmic sperm injection (ICSI) procedures.

K001967

Design Characteristics:

Intracytoplasmic sperm injection (ICSI) procedures are typically performed in those instances where infertility is either caused by severe male factor (i.e. poor quality or insufficient number of sperm) or is of unknown cause, and where traditional in vitro fertilization procedures have not resulted in pregnancy. In ICSI procedures, viable sperm cells are concentrated, purified and then isolated in a culture dish, where a single sperm cell is aspirated into a micropipette or syringe for subsequent injection into an ovum. PVP reagent is used to assist in the immobilization and isolation of the sperm cell prior to ICSI by creating a more viscous environment for the sperm thereby slowing down their movements.

Performance Data:

Polyvinylpyrrolidone reagent is subjected to cytotoxicity testing and sperm motility/hyperactivation analysis. Each lot of PVP reagent is also assayed by a mouse embryo assay prior to its release to market. These assays assure that the product is both functional for its intended use, and that no toxic components are present in the formulation. PVP reagents have been used in a variety of clinical settings, for the intended use for a number of years. In that time the product has become the standard media used for the immobilization and isolation of human sperm cells for use in ICSI procedures.

Additional Information:

Mouse embryo testing will be performed as a condition of release for Polyvinylpyrrolidone reagent as well as endotoxin and sterility testing. Results of all release assays will be reported on a lot-specific certificate of analysis and will be indicated on the labeling.

Conclusion:

The conclusion from performance testing, as well as a review of published historical information contained in the professional literature shows that Polyvinylpyrrolidone reagent is suitable for its intended use and meets the criteria outlined in the Final Rule, 63 FR48428, Docket number 97N-0335.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2000

Robert E. Lovins, Ph.D.
President
InVitroCare, Inc.
11408 Sorrento Valley Rd.
Suite 202
San Diego, CA 92121

Re: K001967
PVP-Polyvinylpyrrolidone Reagent,
Model CAT#2210
Dated: June 28, 2000
Received: June 28, 2000
Regulatory Class: II
21CFR 884.6180/Procode: 85 MQL

Dear Dr. Lovins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

INDICATIONS FOR USE STATEMENT (Page 1 of 1)

510(k) number: K001967

Device Names: PVP-Polyvinylpyrrolidone Reagent

Indications for Use:

PVP (polyvinylpyrrolidone) reagent is intended for use in assisted reproductive technology procedures involving the manipulation of gametes. Specifically, PVP is intended for use as a medium for the immobilization and isolation of single sperm cells during intracytoplasmic sperm injection (ICSI) procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001967

Prescription Use
(per 21 CFR 801.109)